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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,869	11/08/2001	Stewart Paton Granger	J6666(C)	6511

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UNILEVER
PATENT DEPARTMENT
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EXAMINER
BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
1617	2

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Acti n Summary	Application No. 10/007,869	Applicant(s) GRANGER ET AL.	
	Examiner Mojdeh Bahar	Art Unit 1617	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-15 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Warnings

Applicant is advised that should claim 1 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the particular compounds listed in tables B1-B5 on pages 28-29 of the specification, does not reasonably provide enablement for "retinoid boosters" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to

consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines "a retinoid booster". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds, i.e., retinoid boosters, without undue experimentation. In the instant case, a number of "retinoid booster" examples are set forth in tables B1-B5, however, there is no explanation as to what common feature exists among the named examples. It is noted that these examples are neither exhaustive, nor define a particular class of compounds required. What common feature among these compounds exists? Given the wide spectrum of compounds that are represented by the lists provided in Tables B1-B5, e.g., fragrances, flavonoids, different acids, how would the skilles artisan be able to ascertain that a certain compound is a retinoid booster? The pharmaceutical/cosmetic art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "retinoid boosters", necessitating an exhaustive search for the embodiments suitable to practice the claimed

invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "retinoid booster" is indefinite. It is not clear which activities of the retinoid compound is boosted by these retinoid boosters? Further, it is not clear whether a retinoid compound could be a retinoid booster or not?

Claims 5, 10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "mimicking the effect on skin of retinoic acid" is vague and indefinite. What are the effects of retinoic acid on the skin and how are they being "mimicked"? Moreover, these claims depend from independent claims that employ a retinoid compound and therefore possesses and exhibit effects associated with retinoic acid.

The term "stable" in claim 1-3, 6-8 and 11-13 is a relative term which renders the claims indefinite. The term "stable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The degree of stability required is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suares et al. (USPN 5,914,116) in view of Katzung and Remington.

Suares et al. (USPN 5,914,116) teaches a method for a skin treatment comprising a topical application regime and a respective product. The product includes a first composition containing at least one active (0.10% Vitamin A palmitate), and a second composition including a second active (0.30% fragrance, and 3.00% stearic acid). The first and second compositions are stored in respective separate containers, which are joined together, see cols. 7 and 8, Example 1, col. 11, lines 32-36, and abstract in particular. Suares et al. also teaches that coumarines, hydroxycarboxylic acids (including hydroxyoctadecanoic acid), ceramides, phospholipids,

linoleic acid, arachidic acid, phospholipidsimidazolidinyl urea are useful in its compositions, see cols. 4-7.

Suares et al. (USPN 5,914,116) does not teach that the first and/or second compartments keep the respective compositions out of contact with oxygen neither does it teach that the two compartments are made of aluminum.

Katzung teaches that retinoic acid is easily oxidized, page 940.

Remington in a subsection entitled pharmaceutical containers in the chapter on stability of pharmaceutical products teaches that aluminum containers are widely used in the pharmaceutical products. Remington also teaches that this metal presently offers the widest range of lining possibilities, 1510-1512.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to keep the compositions out of contact with oxygen and to employ aluminum compartments.

One of ordinary skill in the art would have been motivated to keep the compositions out of contact with oxygen because retinoic acid is known to be easily oxidated. One of ordinary skill would have also been motivated to keep the compositions in an aluminum because these types of containers are widely used in order to preserve the stability of pharmaceutical products.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 on Monday, Tuesday, Thursday and Friday from 8:30 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
February 21, 2002

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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